

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

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IN RE:

MASTER FILE

00 Civ. 2843 (LAK)

REZULIN PRODUCTS LIABILITY
LITIGATION (MDL-1348)

This Document Relates To: All Cases

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PRETRIAL ORDER NO. 49
(Confidentiality of Third Party Documents)

Lewis A. Kaplan, *District Judge*.

To expedite the flow of discovery material, facilitate the prompt resolution of disputes over confidentiality, adequately protect material entitled to be kept confidential, and ensure that protection is afforded only to material so entitled, pursuant to the Court's authority under Federal Rule of Civil Procedure 26(c), it is hereby:

ORDERED, as follows with respect to documents and things produced or made available for inspection and designation for copying by any third party ("Third Party") with respect to MDL 1348. This Order is not applicable to documents and things produced or made available for inspection and copying by defendant Warner-Lambert Company ("Warner-Lambert"), Parke-Davis, an unincorporated division of Warner-Lambert Company, and all others associated with them (collectively known as "Warner-Lambert Defendants"), which instead are subject to Pretrial Order No. 3:

1. **Nondisclosure of Confidential Documents.** Except with the prior consent of Third Party, no Confidential Document, as hereinafter defined, or the substance of such Confidential Document, may be disclosed to any person except as provided in paragraph 4.

2. Definitions

2.1 For purposes of this Order, the term “document” means all written, recorded, or graphic material produced by Third Party and whether produced pursuant to Rule 34, subpoena, by agreement, or otherwise. Responses to subpoena, deposition transcripts and exhibits, pleadings, motions, affidavits, and briefs that quote, summarize, or contain materials entitled to protection may be accorded status as a Confidential Document as provided herein, but, to the extent feasible, shall be prepared in such a manner that the confidential information is bound separately from that not entitled to protection.

2.2 The term “Confidential Document” shall mean any document produced by Third Party which bears the legend (or which shall otherwise have had the legend recorded upon it in a way that brings it to the attention of a reasonable examiner) “Confidential—Subject to Protective Order” or “Confidential—Subject to Protective Order in Rezulin® Related Litigation” (hereinafter “Confidentiality Legend”) and the date to signify that it contains information believed to be subject to protection under Fed. R. Civ. P. 26(c).

3. Redaction of Documents

3.1 Notwithstanding the provisions of paragraph 1 above, Third Party may redact from any Confidential Document any trade secrets or other highly confidential research, development or commercial information, including but not limited to:

- 3.1.1 specific dollar amounts;
- 3.1.2 specific manufacturing dimensions or tolerances;
- 3.1.3 chemical formulas or methods of synthesization;
- 3.1.4 specific product specifications including, but not limited to, information relating to software object and source codes;
- 3.1.5 specific customer or supplier identities;
- 3.1.6 manufacturing methods and processes; and
- 3.1.7 names and any information that would identify clinical trial subjects or patients (other than the parties) referred to in subjects or patients (other than the parties) referred to in adverse reaction reports, product experience reports, consumer complaints and other similar data and any third party involved with such subjects or patients, including but not limited to a physician or hospital or other institution.

3.2 Upon request, the attorney members of the PEC may inspect, on an “attorneys’ eyes only” basis, material redacted pursuant to this paragraph. If there is a dispute whether any redacted material qualifies for redaction under this paragraph, counsel may move for a ruling, which may require this Court’s *in camera* inspection of a document on the issue of whether certain information is entitled to redaction.

3.3 Notwithstanding the provisions of paragraph 1 above, the parties recognize that when large volumes of documents are provided to counsel for inspection and designation for copying, the documents may not have yet been reviewed for confidentiality purposes, and the right is reserved for Third Party to so designate and

redact appropriate documents after they are produced by Third Party. During the inspection process, all documents reviewed by the parties' counsel shall be treated as Confidential Documents.

4. Post-Production Designation.

4.1 Within 21 days after a Third Party's production of documents, such Third Party may designate such documents as Confidential Documents which had not been so previously designated during the initial production. Such Third Party shall do so by forwarding within such time period to the requesting party to whom it originally produced the documents new copies of the documents which are marked in accordance with Paragraph 2.2 herein. Upon receipt of such newly designated documents, the requesting party to whom the documents were produced shall ensure that previously produced documents are replaced with the newly marked Confidential Documents, and that the previously marked copies of the documents are destroyed or returned to such Third Party.

4.2 Within 21 days after receipt by the Warner Lambert Defendants of Third Party documents produced to a requesting party, Warner Lambert may designate such documents as Confidential Documents in accordance with the provisions of Pretrial Order No. 3 which were not designated as Confidential Documents by the Third Party at the time of production to the requesting party. The Warner Lambert defendants shall do so by forwarding within such time period to the requesting party to whom the Third Party originally produced the documents new copies of the documents which are marked in accordance with Paragraph 2.2 of Pretrial Order No. 3. Upon receipt of such newly

designated documents, the requesting party to whom the documents were produced shall ensure that previously produced documents are replaced with the newly marked Confidential Documents, and that the previously marked copies of the documents are destroyed or returned to the Warner Lambert Defendants.

5. Permissible Disclosures. Notwithstanding paragraph 1, Confidential Documents may be disclosed to counsel for the parties in this action who are actively engaged in the conduct of this lawsuit; to the partners, associates, secretaries, paralegal assistants, and employees of such counsel to the extent reasonably necessary to render professional services in the lawsuit; to persons with prior knowledge of the documents or the confidential information contained therein, and their agents; and to court officials involved in this lawsuit (including court reporters, persons operating video recording equipment at depositions, and any special master appointed by the Court). Subject to the provisions of subparagraph (c), such documents may also be disclosed:

- (1) to any person designated by the Court in the interest of justice, upon such terms as the Court may deem proper;
- (2) to persons noticed for depositions or designated as trial witnesses to the extent reasonably necessary in preparing to testify; to outside consultants, co-counsel or experts retained for the purpose of assisting counsel in the lawsuit; to third parties engaged solely in one or more aspects of organizing, filing, coding, converting, storing, or retrieving data or designing programs for handling data connected with this lawsuit, including the performance of such duties in relation to a computerized litigation support system; provided, however, that in all such cases the individual to whom disclosure is to be

made under this subparagraph (b) has signed the Agreement to Maintain Confidentiality in the form attached hereto, which shall be maintained by the PEC and, if requested, submitted to the Court for *in camera* review;

- (3) to representatives of the United States Food and Drug Administration (“FDA”), or, if pursuant to subpoena, to any other government agency. Prior to any such disclosure, the PEC or other disclosing person must advise the government agency or representatives thereof receiving the disclosure of the provisions of this order.
- (4) Before disclosing a Confidential Document to any person listed in subparagraphs (a)-(b) who is a competitor (or an employee of a consultant to a competitor) of Third Party or any governmental representative pursuant to subparagraph (c), the parties shall give at least ten days’ advance notice in writing to Third Party stating the names and addresses of the person(s) to whom the disclosure will be made, and stating the purposes of such disclosure. If, within the ten-day period, a motion is filed objecting to the proposed disclosure, disclosure is not permissible until and unless the Court denies such motion.
- (5) Documents designated as CONFIDENTIAL and produced in this matter may also be disclosed to counsel representing plaintiffs in other Rezulin-related litigations against Warner-Lambert, if all of the following conditions are met:

- (a) counsel receiving CONFIDENTIAL documents pursuant to this paragraph must in writing
 - (i) agree to be bound by the terms of this Protective Order, and
 - (ii) submit to the jurisdiction of this Court for purposes of enforcement of this Protective Order against them; and
- (b) a protective order of confidentiality on substantially identical terms to this one, or on such other terms as Third Party may agree to, shall have been entered in each pending case in which such counsel wishes to use documents disclosed under this paragraph; and
- (c) counsel receiving CONFIDENTIAL documents pursuant to this paragraph agree to stipulate promptly to entry of a protective order of confidentiality on substantially identical terms as this one, or on such other terms as the parties may agree to, in any new cases that they may bring related to Rezulin in which they seek to use any such documents.

6. Challenges to Confidentiality Designations. The parties may apply to the Court for a ruling that a document (or category of documents) designated as a Confidential Document(s) is not entitled to such status and protection. Before any such application is filed, counsel for the parties and Third Party (or counsel for Third Party if represented by counsel) shall attempt to resolve the issue through discussions. If such discussions are unsuccessful and a party files an application, Third Party shall be given notice of the application and an opportunity to respond. To maintain

confidential status, the proponent of confidentiality must show by a preponderance of the evidence that there is good cause for the document to have such protection.

7. Confidential Information in Depositions

7.1 A deponent may during the deposition be shown and examined about Confidential Documents pursuant to the provisions of paragraph 4(b). Deponents shall not be entitled to retain permanently or copy portions of the transcripts of their depositions that contain confidential information not provided by them or the entities they represent, but shall instead be required to return that information to counsel at the conclusion of the litigation, unless they sign the form described in paragraph 4(b). A deponent who is not a party or Third Party or a representative of a party or Third Party shall be furnished a copy of this Order before being examined about, or asked to produce, potentially Confidential Documents.

7.2 Parties and subpoenaed Third Parties (and deponents) may, within thirty days after receiving a deposition, designate pages of a transcript (and exhibits thereto) as confidential. Confidential information within the deposition transcript may be designated by underlining the portions of the pages that are confidential and marking such pages with the following or similar legend: “Confidential—Subject to Protective Order.” Until expiration of the thirty day period, the entire deposition will be treated as subject to protection against disclosure under this Order. If no party, subpoenaed Third Party or deponent timely designates confidential information in a deposition, then none of the transcript or its exhibits will be treated as confidential; if a timely designation is made,

the confidential portions and exhibits shall be filed under seal separate from the portions and exhibits not so marked.

7.3 The provisions of paragraph 5 above shall apply in the event a party opposes the post-deposition designation of materials or testimony as confidential.

8. Confidential Information at Trial or Hearing. Subject to the Federal Rules of Evidence, Confidential Documents and other confidential information may be offered in evidence at trial or any court hearing, provided that the proponent of the evidence gives fifteen (15) days' advance notice to Third Party. Any party or Third Party may move the court for an Order that the evidence be received *in camera* or under other conditions to prevent unnecessary disclosure. The court will then determine whether the proffered evidence should continue to be treated as confidential information and, if so, what protection, if any, may be afforded to such information at trial.

9. Subpoena by Other Courts or Agencies. If another court or an administrative agency subpoenas or orders production of Confidential Documents that the parties have obtained under the terms of this Order, the parties shall promptly notify Third Party of the pendency of such subpoena or order.

10. Filing. Confidential Documents need not be filed with the clerk except when required in connection with motions under Fed. R. Civ. P. 12 or 56 or other matters pending before the court. If filed, they shall be filed under seal and shall remain sealed while in the office of the clerk so long as they retain their status as Confidential Documents.

11. Client Consultations. Nothing in this Order shall prevent or otherwise restrict counsel from rendering advice to their clients and, in the course thereof, relying generally on examination of Confidential Documents; provided, however, that in rendering such advice and

otherwise communicating with such clients, counsel shall not make specific disclosure of any item so designated except pursuant to the procedures of paragraph 4(b) and (c).

12. Use. Persons obtaining access to Confidential Documents under this Order shall use the information only for preparation and trial of cases docketed in MDL 1348 (including trials, appeals and retrials of such cases after remand to a transferor court), and shall not use such information for any other purposes, including business, governmental, commercial, administrative, or judicial proceedings.

13. Non-Termination. The provisions of this Order shall not terminate at the conclusion of this action. This Order shall remain in full force and effect and each person subject to this Order shall continue to be subject to the jurisdiction of this Court for the purposes of enforcement of the confidentiality terms of this Order. Within 120 days after final conclusion of all aspects of this lawsuit, Confidential Documents and all copies of same (other than exhibits of record) shall be returned to the Third Parties who produced the documents or shall be destroyed. All counsel of record shall make certification of compliance herewith and identifying the Third Party sources of the returned or destroyed documents. Said certification shall be delivered to Plaintiffs' Liaison Counsel, Lieff, Cabraser, Heimann & Bernstein, 780 Third Avenue, 48th Floor, New York, NY 10017, attention Steven E. Fineman. Should any Third Party wish to obtain copies of such certifications, they shall submit their names and mailing addresses to Plaintiffs' Liaison Counsel, who shall mail all certifications to such requesting Third Parties within 150 days of the conclusion of the litigation.

14. Modification Permitted. Nothing in this Order shall prevent a party or Third Party from seeking modification of this Order, or from objecting to discovery that it believes otherwise to be improper.

15. Responsibility of Attorneys. The attorneys of record are responsible for employing reasonable measures, consistent with this Order, to control duplication of, access to, and distribution of Confidential Documents. Parties shall not duplicate any Confidential Document except working copies and for filing in court under seal. All copies made of Confidential Documents shall bear the confidential designation.

16. No Waiver.

16.1 Review of the Confidential Documents and information by counsel, experts or consultants for the litigants in the lawsuit shall not waive the confidentiality of the documents or objections to production.

16.2 The inadvertent, unintentional, or in camera disclosure of Confidential Documents and information shall not, under any circumstances, be deemed a waiver, in whole or in part, of any party's claims of confidentiality.

17. Nothing contained in this Protective Order and no action taken pursuant to it shall prejudice the right of any party to contest the alleged confidentiality, relevancy, admissibility, or discoverability of the Confidential Documents and information sought.

18. Nothing contained in this Protective Order shall preclude the parties from alternatively reaching a separate agreement or arrangement concerning the confidentiality of documents produced in this litigation, or mutually agreeing to the application of any other Pretrial Order entered in this litigation.

19. No document shall be deemed Confidential under this order if it has been produced as non-confidential, by agreement or court order, in any other case.

20. This Protective Order will bind the parties and their counsel in all cases docketed in MDL 1348 and will remain in effect in all such cases after remand to transferor courts.

SO ORDERED.

Dated: January 25, 2002

Lewis A. Kaplan
United States District Judge